

SERENACE 500 microgram CAPSULES

Haloperidol

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. WHAT SERENACE IS AND WHAT IT IS USED FOR

Serenace Capsules contain haloperidol, which belongs to a group of drugs known as antipsychotics.

Serenace Capsules are used to treat:

- schizophrenia and other similar mental disorders such as mania (feeling elated or over-excited, which causes unusual behaviour), and paranoia, violent or dangerous impulsive behaviour
- aggression, overactivity and self-mutilation in patients who are mentally ill and are likely to behave dangerously
- Tourette's syndrome, tics (repeated and largely involuntary movements)
- restlessness and agitation in the elderly
- nausea and vomiting
- with other therapy, the short-term management of anxiety
- behavioural disorders in children, especially those associated with hyperactivity and aggression.

2. BEFORE YOU TAKE SERENACE

DO NOT take Serenace and talk to your doctor if you:

- are allergic (hypersensitive) to haloperidol or any of the other ingredients of this medicine
- are breast-feeding
- have been told by your doctor that you have a condition that affects part of your brain called the "basal ganglia"
- suffer from Parkinson's disease, Huntington's Chorea or a related movement disorder
- suffer from uncorrected hypokalaemia (low levels of potassium in the body)
- have severe heart problems e.g. recent heart attack, heart failure, irregular heart beat for which you need to take medicine
- have a family history of unexplained fainting, blackouts or heart attacks
- are taking certain other medicines which can affect the heart (see 'Taking other medicines')

- have a rare hereditary problem of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption
- are less aware of things around you or your reactions become slower.

Serenace should not be given to patients if they are in a coma.

Warnings and precautions

Take special care with Serenace

Talk to your doctor before you start to take this medicine if you:

- are elderly as you may be more sensitive to the effects of Serenace
- are at risk of blood clot in the vein (deep vein thrombosis)
- have or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- suffer from epilepsy or conditions that might cause epilepsy such as alcohol withdrawal or brain damage
- have diseased arteries
- suffer from dementia
- suffer from depression
- have low blood pressure, calcium or magnesium levels or have not eaten for a prolonged length of time
- have problems with alcohol abuse or alcoholism
- have ever had any problems with your liver, kidneys or heart, or there is a history in your family of heart problems or sudden death
- have ever had a stroke, transient ischaemic attack (TIA) or have a family history of strokes
- have ever had a growth in your adrenal gland (phaeochromocytoma) or trouble with your thyroid gland, which causes too much thyroid hormone to be made (thyrotoxicosis)
- have been fasting.

You may need to be more closely monitored, and the amount of Serenace Capsules you take may have to be altered. If you are not sure if any of the above apply to you, talk to your pharmacist before taking Serenace Capsules.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Serenace Capsules. The ECG measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of minerals (electrolytes) in your blood.

Available safety data in the paediatric population indicate a risk of extrapyramidal symptoms, including tardive dyskinesia (involuntary, repetitive body movements), and sedation. No long-term safety data available.

Taking other medicines

Special monitoring may be needed if you are taking lithium and Serenace Capsules at the same time. Tell your doctor straight away and stop taking both medicines if you get:

- confused, disoriented, a headache, balance problems and feel sleepy. These are signs of serious conditions.

DO NOT take Serenace if you are taking:

- certain other medicines which can affect the heart e.g. quinidine, bretylium, disopyramide, procainamide, amiodarone, sotalol, dofetilide.

Talk to your doctor if you are taking any of the following:

- any other medicine similar to Serenace known as a neuroleptic e.g. phenothiazines, sertindole, pimozone, promazine, amisulpride
- certain medicines for the treatment of depression e.g. fluoxetine, amitriptyline, maprotiline, lithium, paroxetine
- sleeping capsules, sedatives or strong pain killers
- medicines for changes in your heart beat or are taking medicines that affect your heart beat
- medicines which can affect the chemicals in your bloodstream known as electrolytes, such as diuretics, e.g. furosemide
- certain antibiotics e.g. moxifloxacin, sparfloxacin, erythromycin
- levodopa, for Parkinson's disease
- buspirone, for anxiety
- quinine and mefloquine, for malaria
- indometacin, for rheumatoid arthritis
- methyldopa, to lower your blood pressure
- carbamazepine, for epilepsy
- any antihistamine, for an allergy or hay-fever
- sympathomimetic agents e.g. found in cold and flu remedies – please check with your pharmacist
- adrenaline, used in emergency situations e.g. to treat severe allergic reactions
- medicines for thinning the blood, such as phenindione
- medicines for a fungal infection, such as ketoconazole
- levothyroxine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you suffer from a disorder with related memory loss, you should talk first to your doctor, who will decide if you can be given Serenace and will explain the possible risks of its use.

Important information about some of the ingredients of Serenace

- Patients who are intolerant to **lactose** should note that Serenace capsules contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains **tartrazine (E102)** as a colouring agent. It can cause allergic type reactions including asthma. If you are allergic to aspirin, you are more likely to suffer a reaction.

Taking Serenace with food and drink

- DO NOT drink alcohol whilst taking Serenace.

Pregnancy and breast-feeding

- The following symptoms may occur in newborn babies, of mothers that have used Serenace in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.
- DO NOT take Serenace if you are breast-feeding. This is because small amounts may pass into mother's milk.
- If you are pregnant or planning to become pregnant ask your doctor for advice before taking this medicine.

Driving and using machines

- Serenace may cause drowsiness or impaired alertness, especially at the start of treatment. If you are affected, DO NOT drive or operate machinery without discussing this with your doctor first.

3. HOW TO TAKE SERENACE

Always take Serenace exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You may not feel better for several weeks after you start to take your capsules.

The capsules should be swallowed whole preferably with a drink of water.

If you are taking high doses of Serenace, your doctor will give you a higher strength product so that you do not need to take a large number of capsules each day. The usual dose is:

Adults

- **Psychotic and behavioural conditions:**
The usual starting dose is between 1.5 mg (3 capsules) and 20 mg (40 capsules) a day, taken either as a single dose or two smaller doses.
Your doctor may increase this dose up to a maximum of 30 mg a day (60 capsules) in some cases.
When your doctor is happy that you are responding to your treatment, they may gradually reduce the dose. This could be as low as 3 mg (6 capsules) to 10 mg (20 capsules) daily.
- **Tourette's Syndrome:**
The starting dose is usually 2 mg (4 capsules) a day.
Your doctor may increase this dose to between 6 mg (12 capsules) and 30 mg (60 capsules) a day in some cases.
When your symptoms are controlled your doctor will gradually reduce your dose to around 4 mg (8 capsules) a day.
- **Nausea and vomiting:**
The usual dose is 1 mg (2 capsules) a day.
- **Anxiety:**
The usual dose is 500 micrograms (1 capsule) twice a day.

The Elderly

If you are elderly, your doctor will probably give you half the doses mentioned above.

Children

Your doctor will work out the dose depending on your child's weight. The usual dose is 25 to 50 micrograms for each kilogram (kg) of body weight up to a maximum of 10 mg. Teenagers may be given up to 30 mg a day.

If you take more Serenace than you should

If you (or someone else) swallow a lot of the capsules all together, or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause muscle weakness, muscle stiffness, shaking, low blood pressure, drowsiness.

Please take this leaflet, any remaining capsules and the container with you to the hospital or doctor so that they know which capsules were consumed.

If you forget to take Serenace Capsules

If you forget to take a capsule, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose. If it is nearly time to take the next dose, wait until then and then carry on as before.

If you stop taking Serenace

DO NOT stop taking Serenace without talking to your doctor first even if you feel better.

When you stop taking Serenace, your doctor will reduce the dose gradually to avoid the possibility of withdrawal symptoms, such as feeling and being sick and being unable to sleep, or the recurrence of your original condition.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Serenace can cause side effects, although not everybody gets them.

Stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing, severe skin rash or hives.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

See your doctor immediately if you suffer from any of the following, as your treatment will need to be reviewed:

- uncontrolled movements, especially in your limbs and face, mouth and jaw, tremors, tics and muscle spasm in your shoulders, neck, body and arms. These are very common side effects. However rarely this can be severe enough to cause breathing difficulties. The first signs may be uncontrolled movements of your tongue.
- your muscles begin to feel rigid; body adopts rigid posture or a mask like face. These are common side effects.
- extreme restlessness, loss of normal muscle control, difficulty in moving, shakiness and loss of movement
- you feel feverish and become less alert than usual, or you feel hot, you start sweating and your heartbeat speeds up
- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing
- in elderly people with dementia, a small increase in the number of deaths has been reported for

patients taking antipsychotics compared with those not receiving antipsychotics

- a serious problem called “neuroleptic malignant syndrome”. The signs may include:
 - Fast heart beat, changing blood pressure and sweating followed by fever
 - Faster breathing, muscle stiffness, reduced consciousness and coma
 - Raised levels of a protein in your blood (an enzyme called creatine phosphokinase)
- an uncontrolled muscular contraction (spasm) of the laryngeal cords associated with purple coloration of the skin, tongue-tie, difficulty in breathing and to the psychological experience associated with such difficulty, deficient supply of oxygen to the body.

If you notice any of these symptoms seek medical advice immediately.

You may also experience difficulties with sex such as: erectile dysfunction (inability to develop or maintain an erection of the penis), decreased sexual desire, and some men may experience swelling of the breasts or painful and prolonged erection.

The following side effects have been reported at the approximate frequencies shown:

Very common (affecting more than one person in 10):

- feeling agitated or having difficulty sleeping
- headache.

Common (affecting less than one person in 10 but more than one person in 100):

- depression, mental problems
- rolling of the eyes
- problems with sight
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- constipation, dry mouth, excessive mouth watering, feeling sick, being sick
- abnormal liver function (which may be detected by blood tests)
- rash
- unable to pass urine
- weight changes (increase or decrease)
- dizziness or sleepiness.

Uncommon (affecting less than one person in 100 but more than one person in 1,000):

- a fall in the number of white blood cells which can cause frequent infections
- confusional state
- epileptic fits or seizures (convulsion)
- blurred vision
- rapid heart beat
- shortness of breath
- inflammation of the liver, jaundice (your skin and the whites of your eyes may become yellow) or, due to a change in the way your liver works
- itching, sweating more than usual
- if you are a woman, you may unexpectedly produce milk, having painful breast and your periods may become infrequent or stop
- shuffling, unbalanced walk, neck tilted to one side
- feeling too warm (hyperthermia)
- fluid may build up in your body causing swollen feet or ankles.

Rare (affecting less than one person in 1000 but more than one person in 10,000):

- if you are a woman, your body may make too much of the hormone prolactin
- getting excited, symptoms of psychosis such as abnormal thoughts or vision, or hearing abnormal sounds
- difficulty breathing or wheezing
- difficulties opening the mouth (Trismus)
- muscle twitching
- abnormal heavy and prolonged menstrual periods at regular intervals
- abnormal heart rhythms.

Other side effects

- blood abnormalities, which can cause fever or chills, sore throats and ulcers in your mouth and throat
- feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called ‘syndrome of inappropriate anti-diuretic hormone secretion’ (SIADH).
- low level of blood glucose (hypoglycaemia)
- drowsiness
- vertigo (a sensation that the world is spinning around you)
- heart problems causing symptoms such as palpitations, abnormal heart rhythms, fainting, blackouts or rarely heart attacks
- swelling of the voice box or contraction of the muscle in the voice box
- loss of appetite
- indigestion
- acute liver failure
- inflammation of blood vessels
- flaking or peeling of the skin
- inflamed skin (red, hot to the touch and tender)
- sudden unexplained death has occurred in rare cases but it is not known if this was due to the medicine
- swelling of face
- feeling too cold.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SERENACE

Keep out of the reach and sight of children.

Store the capsules in a dry place below 30°C. Keep them in the original package, do not put them into another container.

Do not use Serenace after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Serenace Capsules contain:

- The active ingredient is haloperidol 500 micrograms

- The other ingredients are lactose and corn starch. The capsule shell contains Titanium Dioxide (E171), Tartrazine (E102), and Patent Blue V (E131). The printing ink contains shellac, black iron oxide (E172) and propylene glycol (E1520).

What Serenace Capsules look like and contents of the pack:

- Serenace Capsules are hard gelatin capsules. Two-tone green printed ‘Norton 500’ on one half and SERENACE on the other.
- The capsules are available in packs of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, 1000 and 5000
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The company responsible for manufacture is Piramal Healthcare UK Limited, Whalton Rd, Morpeth, Northumberland, NE61 3YA.

The Marketing Authorisation holder is Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

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